REMARKS

Reconsideration and re-examination are respectfully requested in view of the below remarks. No amendments have been made to the claims, although they have been included in this response for the convenience of the Examiner.

Rejections under 35 U.S.C. §103

Claims 1-2 and 4-5 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,657,362, hereinafter Giger, in view of U.S. Pub. No. 2002/0101960, hereinafter Nokita. Claims 7 and 25 were rejected under 35 U.S.C. §103(a) as unpatentable over the combination of Giger, Nokita and further in view of Johns. Claims 9-10 were rejected under 35 U.S.C. §103(a) as unpatentable over Giger and Nokita, and further in view of Santurtun. Claims 22-23 and 33 were rejected under 35 U.S.C. §103(a) as unpatentable over Giger and Nokita, and further in view of Saito. Claims 26-27 and 31-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Giger in view of Nokita, Saito and Santurtun. Claims 28-29 were rejected under 35 U.S.C. §103 as unpatentable over Johns in view of Giger and Saito.

Giger:

Giger describes, in the Abstract:

"A method and system for the automated detection of lesions such as masses and/or tissue (parenchymal) distortions in medical images such as mammograms. Dense regions and subcutaneous fat regions within a mammogram are segmented. A background correction may be performed within the dense regions. Hough spectrum within ROIs placed in the breast region of a mammogram are calculated and thresholded using the intensity value .eta. in order to increase sensitivity and reduce the number of false-positive detections. Lesions are detected based on the thresholded Hough spectra. The thresholded Hough spectra are also used to differentiate between benign and malignant masses..."

In particular, a method of Giger is shown in Figure 1 to include steps of digitizing a mammogram (100), border segmentation (101), identification of subcutaneous fat (102), morphological filtering (103), ROI placement 104, Histogram analysis of ROI (105), thresholding (106) and calculation of % density (107).

Thresholding (106) is described in detail in columns 5-6 of Giger with regard to Figures 5A – 6D as a method of subtracting a fatty level from the image. In particular, Giger states that threshold values are determined by evaluating the ROI near the chest wall ["Typically, breasts tend to be dense in the external portions and fatty near the chest wall. Thus the ROI near the chest wall, as compared to that of the entire breast regions can be used to indicate the gray levels of the fatty portions..."] (col. 5, lines 29-334).

Giger further states at column 5, lines 55-60 "Note that small isolated pixels can be removed by processing... with a morphological open operation. This subtraction process can be performed in terms of gray level or in terms of relative x-ray exposure (by use of the characteristic curve of the imaging system)..."

Once the fat is removed, Giger proceeds to identify the density % of the breast. As described at column 6, lines 8-12:

"... Dense portions tend to reside near the nipple and skin region, whereas fatty regions usually can be found along the chest wall in the breast region. By analysis of the histograms, a peak will be located corresponding to the dense region cutoff. The two peaks are used to determine a threshold for fatty and dense pixels. First a digital mammographic image is obtained (step 800) and the dense portion is located (step 801), as described above. Gray-level thresholding will be performed and if the breast is sufficiently dense, background trend correction will be performed within the dense region. For example, a sufficient measure for the percent dense could be 40%. This procedure tends to make the breast "fatty-like" with a more uniform background (in term of denseness). Background trend correction is performed using a 2-dimensional surface fit in which pixels below the threshold (i.e., fatty) are not included in determining the fit (step 802). The 2-D fit is then subtracted from the dense regions (803).

Subtracting the background trend alters average gray value of the resulting image. It is desirable to match the gray-value of the resulting image to the gray level of the original image. The resulting image is normalized to match the average gray level of the ***original image*** (step 804)...[emphasis added by Applicant].

Thus Giger describes a method which "corrects" a background of an image to make it more uniform using a trend correction technique that modifies gray values. In order to ensure that the gray values correspond to gray values of an original image, Giger performs a normalization step. It is important to note here that the Giger technique 'normalizes' based on gray level values of the original image. It is believed that it is an important aspect of the Giger invention to cause the gray level values to revert to their original values to enable accurate feature analysis, as described at column 5, lines 60-64.

Nokita:

Nokita describes "...A radiographic apparatus is disclosed which controls a movement of a reciprocatingly moving grid so that the grid is not or less likely returned in the middle of exposure of an object to X rays. The probability that the object is still exposed to the X rays when the grid is moved in the vicinity of a turning point is thus substantially lowered. Therefore the probability that a resulting radiograph has no or less moiré pattern due to the grid is substantially heightened..."

The Examiner states, at page 5 of the office action, that Nokita "teaches generating a standard-from version ("standard imaging time (an X-ray exposure time)" at para. 0070) of an x-ray medical image (fig. 1, item 180) and subtracting to achieve a standard-form version state (fig. 7, para. 0076).

It is noted that the portion of Nokita identified by the Examiner describes a graph (Figure 7) which plots the interrelationship of the standard X-ray time, exposure time t, the minimum X-ray exposure time Ts, and the maximum X-ray exposure time Te.

Paragraph 0076 states :

[0076] As shown, the abscissa represents the elapsed time (the X-ray exposure time) from when the X-ray emitter 110 has started irradiating the object 120 with the X rays, and the ordinate represents the movement speed of the grid 130. TA2 is a curve representing the maximum X-ray exposure time T.sub.E, namely, the value that is obtained by subtracting the value of TB1 from the value of TA1 shown in FIG. 6. TC2 is a curve representing the minimum X-ray exposure time T.sub.S, namely, the value that is obtained by subtracting the value TB1 from the value of TC1 shown in FIG. 6.

It is noted that Nokita uses the exposure time information *to determine how to control the movement of grid 130.* [See paragraph 0080].

The Examiner states, at page 5 of the office action:

"... It would have been obvious to one of ordinary skill in the art at the time the invention was made for reverting back to the original-form version of *Giger* to be reverting back to a standard-state version as taught by Nokita "to provide a radiographic apparatus, a radiographic method and a computer readable storage medium for acquiring a radiograph, where the probability that a moiré patter in not generated or, is inconspicuous in the radiograph is heightened" *Nokita,* para. 0012.

Applicant's argument

In determining the differences between the prior art and the claims, the question under **35 U.S.C. 103** is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713

F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) .

Claims 1, 2 4 and 5:

Applicant's claim 1 recites :

" A method for computer aided detection of medical abnormalities in x-ray medical images comprising the steps of ...processing a digital or digitized x-ray medical image of an object *to remove distinguishing effects of at least one operating parameter or physical characteristic of an x-ray device* used to form said x-ray medical image ... thereby forming a processed x-ray medical image ... ***processing the processed x-ray medical image according to predetermined values*** for said at least one operating parameter or physical characteristic ***to generate a standard-form version of said x-ray medical image characterizing the x-ray medical image of the object that would have been obtained by the x-ray device using said predetermined values therefor***; and .... processing said standard form version of said x-ray medical image with a computer aided detection algorithm that has been optimized with a plurality of x-ray medical images similarly processed into standard-form versions thereof using the same predetermined values for said at least one operating parameter or physical characteristic; and storing results of the processing of said standard form version of said x-ray medical image with the optimized computer aided detection algorithm...."

The present invention overcomes significant issues encountered by radiologists who need to compare medical images that are generated by different sources. As described at page 4 of Applicant's specification, a radiologist frequently wants to compare one set of mammograms with another set of mammograms, for example, a set of mammograms taken the previous year

for the same person. In such a case there may be significant differences between the two sets, for example, because they were taken on different systems, or recorded on different films, or taken with x-rays of different energy, or for different exposures.

The present invention overcomes these differences though the processing method recited in claim 1, wherein digital x-rays are processed "*to remove distinguishing effects of at least one operating parameter or physical characteristic of an x-ray device*". The images are then processed according to predetermined values to provide "*a standard-form version of said x-ray medical image characterizing the x-ray medical image of the object that would have been obtained by the x-ray device using said predetermined values therefore*" For example, as described at page 8 of Applicant's specification, 'the x-ray energy preferably is set to 25kVp, the exposure to 100mAs, and the breast thickness to 5cm. These parameters are preferred in view of the energy dependence of breast x-ray attenuation..." CAD detection algorithms can then be used to process the standardized images. With such an arrangement, two mammograms taken at different times by different sources can be accurately compared, without distractions caused by differences with x-ray source characteristics.

The combination of Giger and Nokita fail to teach or describe such a system. The Giger system merely describes a method of processing a single image, whereby background correction is performed on dense portions of the image, and the image is 'normalized' by returning it to its original gray values. The Examiner appears to state that the 'normalization' of Giger is analogous to the claimed language of 'processing the processed x-ray medical image according to predetermined values *for said at least one operating parameter or physical characteristic* to generate a standard-form version of said x-ray medical image characterizing the x-ray medical

image of the object that would have been obtained by the x-ray device using said predetermined values therefore..." However, Applicant would submit that such a characterization does not give patentable weight to the claimed term 'predetermined values for said at least one operating parameter or physical characteristic', or the fact that the 'standard-from' is generated to characterize the x-ray medical image as if it 'would have been obtained by the x-ray device *using said predetermined values therefore*... The claims highlight the fact that part of the invention lies in the recognition that a certain values (x-ray energies, breast thickness, etc.) are preferred in view of the energy dependence of breast x-ray attenuation, and the method that is used to ensure that images are processed according to the predetermined values associated with the preferred view.

Although the Examiner appears to rely column 5, lines 55-60 as teaching that the initial image 'processing' may include 'subtraction process... in terms of relative x-ray exposure...', it is noted that the normalization process of Giger describes *only* a modification of gray levels to reach the 'normalized' (original) gray value levels. There is no teaching or suggestion in Giger of "...processing the processed x-ray medical image according to predetermined values for said at least one operating parameter or physical characteristic to generate a standard-form version of said x-ray medical image characterizing the x-ray medical image of the object that would have been obtained by the x-ray device using said predetermined values therefore..." as recited in the claims.

The Examiner admits on page 5 of the office action that "Giger does not disclose generating a standard-form version of said x-ray medical image", but states that Nokita does.

However, Applicant's can find *no teaching or suggestion* in Nokita for generating a **standard-form** medical image. Nokita focuses solely on the movement of an anti-scatter grid. The Examiner relies on the language of Nokita, which uses the language 'standard imaging conditions' . However, even if there were 'imaging' conditions that were 'standard', such a teaching does not describe or suggest an image that has a 'standard-***form***'.

It is further well known that "... A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)..." The Examiner's contention that Giger would somehow be motivated by the use of the term 'standard' in Nokita to modify their invention such that the 'normalization' was to a 'standard form' rather than an original state ignores the explicit teaching in Giger of the need to return the image to the original form to enable accurate execution of CAD tools. It is therefore respectfully requested that the rejection be withdrawn as the proposed modification fails to consider the Giger reference in its entirety.

In addition, although the standards regarding motivation to modify references to meet the claims have recently changes, it is still well known that "... Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)..." The Examiner states that Giger would be motivated to modify its invention (to return to a standard-form rather than an original form, as described) 'to provide a radiographic apparatus ...wherein the probability that a moiré pattern is not generated or is inconspicuous..." With all due respect such motivation does not make sense; Giger is

dealing with processing of images that have already been generated. Nokita is dealing with systems that have vibrating anti-scatter grids that will reduce the moiré pattern on the original image ... *prior to the processing of Giger*. There would be absolutely no reason for Giger to be motivated by Nokita because Giger does not face the problems that are faced by Nokita. Accordingly for the additional reason that the Examiner has failed to provide a motivation for modifying the references, it is requested that the rejection be withdrawn.

Accordingly for at least these reasons it is requested that the rejection of claim 1 be withdrawn. Dependent claims 2, 4 and 5 each serve to further limit it's parent claim 1 and is therefore allowable for at least the reason that it depends from an allowable independent claim. However the claims also include limitations which further distinguish them over the art.

For example, with regard to claim 5, it is noted that Giger neither describes nor suggests "... wherein the processing removes distinguishing effects of the following physical characteristics of the x-ray device ... anode material, source to image distance, anti-scatter grid geometry, film characteristics and screen-film system..." The Examiner states that such a limitation is taught by step 803 of Giger. However, step 803 is a subtraction step that is performed after background trend correction, which is done to make the image more 'fatty like.' There is no mention, description or suggestion of removing *distinguishing effects of ... physical characteristics of the x-ray device* as claims. For this additional reason, it is requested that the rejection of claim 5 be withdrawn.

Claims 7 , 25, 28 and 29:

Claim 7 was rejected under 35 U.S.C. §103(a) as unpatentable over the combination of Giger, Nokita and Johns ["X-ray characterization of normal and neoplastic breast tissues"]. Claim 25 was rejected under Giger, Nokita and Johns and further in view of Saito. Claims 28 and 29 were rejected by the combination of Giger, Nokita and Johns.

Claim 7 recites : The method of claim 1 wherein an x-ray image of a reference material is formed at the same time as the mammogram and under substantially the same conditions, said ***reference material having known x-ray attenuation characteristics representative of different percentages of fat content in the breast***, said method further comprising the step of identifying fat content in the mammogram by comparing exposure values in the mammogram with exposure values on the x-ray image of the reference material..." Claims 25, 28 and 29s similarly include a reference material.

It is first noted that the John reference, which describes attenuation of different materials, fails to overcome the inadequacies described above with regard to the combination of Giger and Nokita. In addition, the John reference fails to state that the x-ray image of the reference material is *formed at the same time as the mammogram and under substantially the same conditions*... For at least this reason, it is respectfully submitted that claims 7, 25 and 29 are patentably distinct over the combination of references and it is requested that the rejection be withdrawn.

Claims 9-10, 26-27, 31-32

Claims 9-10 were rejected under 35 U.S.C. §103(a) as unpatentable over Giger and Nokita, and further in view of Santurtun. Claims 26-27 and 31-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Giger in view of Nokita, Saito and Santurtun.

Santurtun:

Santurtun describes, in the Abstract, an "X-ray generator system is provided with a high-voltage feedback loop for controlling the output of an inverter to thereby maintain a desired output voltage level. The voltage-feedback loop is provided with a phase-advance network to selectively vary the gain of the system in such a way as to provide for high gain during the initial stage so as to obtain a short rise time, while subsequently reducing the gain so as to clamp the kV overshoot at the end of the rise time. A phase-lag network is also included to effectively eliminate noise that is introduced by the phase-advance network..." The Examiner appears to rely on Santurun's mention of an x-ray energy having a range of 25-28 kVp as teaching the limitations of the claimed invention.

However, even if Santurtun mentions a typically used kVp and mA, there is no mention or suggestion in Santurtun of a *standard-form image*, which has been generated by processing using predetermined values. Thus, Santurtun fails to overcome the inadequacies described above in the combination of Giger and Nokita.

For at least these reasons it is requested that the rejection of claims 9-10 and 26-27 and 31-32 be withdrawn.

Claims 22-23 and 33

Claims 22-23 and 33 were rejected under 35 U.S.C. §103(a) as unpatentable over Giger and Nokita, and further in view of Saito.

Saito:

Saito describes, in the Abstract "... A display screen of an image display section is divided into an image display area for displaying an image and an operation panel display area, an image (base image) imaged by an X-ray CT apparatus, for example, is displayed on the upper part (base area) of the image display area, an image (match image) imaged by a MRI apparatus is displayed in the middle part (match area), and an operation panel, which is composed of an operation panel display area 2 of the image display section and respective operation keys for aligning the images, is displayed thereon. When the operation panel is operated and fit points are provided to the images or a region of interest (ROI) is set on the base image, a CPU aligns and composes the respective images based on the fit points or ROI, and displays the fusion image on the lower part (fusion area) of the image display area. As a result, both the images can be compared with each other visually..."

Thus Saito describes a system where images from different sources are aligned on a display device for viewing.

Claim 22 recites the steps of : "processing a plurality of digital or digitized mammograms formed by different x-ray mammography systems to remove effects of each mammography system and fat content in the breast being imaged, thereby forming first processed images; *converting each first processed image into a standard-form x-ray mammogram having a first standard x-ray voltage parameter and a first standard exposure parameter* ... " As described above, while Giger may process *a* digitized mammogram to remove effects using a subtraction technique described at column 5 'in terms of gray levels or x-ray exposures', the Examiner has maintained that the *converting* of this image is analogous to the step of normalization in Giger.

There is no mention or suggestion in Giger that the normalization is performed based on *first original x-ray voltage parameter and first original exposure parameter* as claimed. Rather, Giger mentions only that normalization 'match(es) the average gray level of the original image).

Saito fails to overcome any deficiencies in Giger and the combination of remaining references. For at least this reason it is requested that the rejection of the claims be withdrawn.

Conclusion

Accordingly, in view of the above remarks it is believed that this application is now in condition for allowance, and a notice to this effect is therefore solicited.

If the Examiner believes a telephone interview would expedite prosecution of this application, the Examiner is invited to call applicant's attorney at the number given below.

Respectfully submitted,

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